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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,790	05/24/2000	Antonio Moroni	498-206	4530

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT PAPER NUMBER

3738

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/577,790

Applicant(s)

MORONI, ANTONIO

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-15, 17, 19, 21, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 8-15, 17, 19, 21, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/2/05 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3,5,6,9-15,17,19,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt (5443499) in view of Kramer et al. (5871468). Schmitt discloses a tubular fabric for use as a vascular prosthesis or as an intraluminal prosthesis, col. 2, lines 15-20. Schmitt also discloses a prosthesis that has 115 denier and 100 filaments that are partially oriented to be used for graft material and can be attached with a stent, col. 7, lines 31-44. Schmitt discloses the plurality of polymeric filaments comprise a combination of undrawn and partially drawn radial filaments, col. 4, lines 51-58, col. 6, lines 48-57. Schmitt additionally discloses the stent and fabric can be integrated such that controlled radial expansion can be achieved based upon the force exerted, col. 4, lines 65-68 and col. 5, lines 1,2. Schmitt does disclose that polymers,

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i.e. polypropylenes and copolymers can be used for the filaments, col. 6, lines 21-25.

However, Schmitt does not disclose the polymeric filaments are made of a naphthalate copolymer. Kramer et al. teach the use of biocompatible polyester fibers such as polyethylene naphthalate (PEN) and polybutylene naphthalate are used for medical devices, col. 4, lines 32-35,41,42. Kramer also discloses that polyester blends form a stable, structurally integral, and material that resists excessive expansion upon internal expansion, col. 4, lines 2-7. The examiner asserts that the claimed physical properties and formula (in this case, the material being radiation resistant and hydrolytically stable) are present in the Kramer material to some extent even though they are not explicitly recited. All materials can be considered radiation resistant, since they are inherently exposed to some sort of radiation, such as radio waves, visible radiation from lights, etc. or possibly UV radiation. Since there is no objective or quantitative measurements as to ascertain what is considered "radiation resistant" or "hydrolytically stable" the properties are inherently possessed by the prior art material. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art. The fabric is inherently stable at least *about* 120°C because this temperature is well below the melting point of PEN, which is 270°C. It would have been an obvious matter of design choice to modify the naphthalene material used, since applicant has not disclosed that using combinations of naphthalene or i.e. PEN and PBN provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the PEN or PBN amounts in the filaments taught by Kramer or

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the claimed combinations of naphthalene compounds in claim(s) 1,11,17,23 because both compounds perform the same function of being radiation resistant and stable for use as an implant material in the Schmitt prosthesis to provide a more structurally stable implant.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt '499 in view of Kramer et al. '468 as applied to claim 1 above, and further in view of Kuwahara (WO 99/04727). Schmitt in view of Kramer is explained supra. However, Schmitt as modified by Kramer fail to disclose a coating on the prosthesis. Kuwahara teaches the prosthesis can have a coating, col. 4, lines 65-67. It would have been obvious to one of ordinary skill in the art to use a therapeutic coating on the prosthesis as taught by Kuwahara in the implant of Schmitt as modified by Kramer such that it provides the ability to treat the area of the implant.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt '499 in view of Kramer et al. '468 and Schmitt et al. (5697970). Schmitt is explained supra. Kramer is explained supra. However, Schmitt and Kramer do not disclose the prosthesis comprising a series of crimps. Schmitt et al. '970 teach (Figs. 1,2) that crimps are applied to graft prostheses for enhancing pliability, ease of handling and structural stability, col. 3, lines 14-43. It would have been obvious to one of ordinary skill in the art to incorporate at least two naphthalene dicarboxylate derived polymers for the filaments as taught by Kramer and use crimps as taught by Schmitt '970 with the prosthesis of Schmitt '499 such that it is more flexible and improve the chemical stability of the implant.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt (5443499) in view of Kuwahara (WO 99/04727). Schmitt discloses a tubular fabric for use as a vascular prosthesis or as an intraluminal prosthesis, col. 2, lines 15-20.

Schmitt also discloses the plurality of polymeric filaments comprise a combination of undrawn and partially drawn radial filaments, col. 4, lines 51-58, col. 6, lines 48-57.

However, Schmitt does not disclose the polymeric filaments are made of a naphthalene derivative. Kuwahara is explained supra. It would have been obvious to one of ordinary skill in the art to use naphthalene dicarboxylate derived polymeric filaments as taught by Kuwahara in the Schmitt prosthesis to provide a more stable implant.

Response to Arguments

Applicant's arguments with respect to claims 1,11,17,21,23,24 have been considered but are moot in view of the new ground(s) of rejection. Applicant argues that Kramer does not disclose combinations of naphthalene compounds for the medical device. It is noted that Kramer discloses that PEN and PBN can be used alternatively or in other words these compounds provide the equivalent effect. Since Applicant failed to indicate where in the written disclosure that the combination of naphthalene materials is critical to be used for the filaments, it appears that an obvious matter of design choice to utilize both compounds is an appropriate grounds for rejection of the claims. Applicant also argues that Schmitt does not teach the limitation of both "undrawn and drawn yarns in the radial direction" of which is supported by Figs. 1 and 2 as stated by Applicant on

page 8 of the response. Since the patent to Schmitt has the same figures it must inherently have "both undrawn and drawn yarns in the radial direction".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).